K092432
#1/2

Attachment 4

510(k) Summary

[As Required by 21 CFR 807.92]

OCT - 9 2009

Date Prepared: July 30, 2009

Submitter:
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Establishment Registration Number: 9616164

Contact Person:
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Republic of Korea
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Trade Name: Automatic Blood Pressure Monitor
Models EASY X 800(R/L) & EASY X 900 (R/L)

Common Name: Blood Pressure Monitor

Classification Name: Non-Invasive Blood Pressure Measurement System; 21CFR870.1130 (DXN)

Predicate Device: Automatic Blood Pressure Monitor, Models FT-500 (R/L) and FT-700 (R/L)
(K062462, Sep. 29, 2006)

Device Description:

The EASY X 800 (R/L) and EASY 900 (R/L) are blood pressure monitors to non-invasively measure blood pressure and heart rate at the brachial site. The devices employ oscillometric method. The devices are microprocessor-controlled and include an air pump, an electronic valve to regulate deflation rate, circuitry to detect and process minute pressure oscillations, LED(EASY X 800) or LCD(EASY X 900) display of systolic and diastolic pressure readings and heart rate, and push buttons.

The devices employ a pressure measurement algorithm designed to detect, filter, process, and store pressure readings. The electronic deflation control valve maintains the deflation rate within limits of 3 to 5 mmHg/sec to optimize measurement accuracy.

The EASY X 800 (R/L) and EASY X 900 (R/L) are AC adapter-powered.

Intended use:

Automatic Blood Pressure Monitor Models EASY X 800 (R/L) and EASY 900 (R/L) are intended for the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients with age 16 or order and arm circumference range between 9" to 14" (23cm to 36cm).

Technologic characteristics:

The modified devices EASY X 800 (R/L) and EASY 900 (R/L) have the same intended use and technology characteristics as predicate devices FT-500 (R/L) and FT-700 (R/L). The differences in this submission don't raise new questions concerning either safety or effectiveness.

Non-clinical and clinical tests:

The modified devices EASY X 800 (R/L) and EASY 900 (R/L) meet the requirements of ANSI/AAMI SP10, IEC 60601-1, and EN 60601-1-2. The EASY X 800 (R/L) and EASY X 900 (R/L) are not clinically tested because the devices use the identical software codes and pressure detection related hardware as the predicate devices to determine systolic, diastolic, and pulse rate.

Conclusions:

Based on the non-clinical tests, the modified devices EASY X 800 (R/L) and EASY 900 (R/L) are as safe, as effective, and perform as well as the predicate devices FT-500 (R/L) and FT-700 (R/L). Accordingly the modified devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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c/o Mr. H. L. Jung
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REPUBLIC OF KOREA

OCT - 9 2009

Re: K092432
Trade/Device Name: Jawon Medical Automatic Blood Pressure Monitor, Models EASY X 800 (R/L) & EASY X 900 (R/L)
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: August 8, 2009
Received: September 14, 2009

Dear Mr. Jung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. A. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092432

Attachment 1

Indications for Use Statement

510(k) Number (if known): K092432

Device Name: Jawon Medical Automatic Blood Pressure Monitor
Models EASY X 800 (R/L) & EASY X 900 (R/L)

Indications for Use:

Noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients with age 16 or older and arm circumference range between 9" to 14" (23cm to 36cm).

Prescription Use ____ AND/OR Over-The-Counter Use ✓
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE NO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division [illegible]

510(k) Number K092432